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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,277	10/20/2003	Eddie F. Ray III	4002-3433/PC545.02	2922
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 05/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,277

Applicant(s)

RAY ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-19, 27-32, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-19, 27-32, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-19, 27-32, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Pat. 5,484,437).

Michelson discloses a spinal instrument assembly, comprising: a guide sleeve housing (Fig. 7F) including a proximal portion (Fig. 7F, portion near ref. 352) and a distal portion (Fig. 7F, portion near ref. 344), said proximal portion including an inner wall (Fig. 7F, inner wall near ref. 352) defining a proximal chamber (Fig. 7F, ref. chamber formed by inner wall near ref. 352), said housing further including a first working channel port (Fig. 7F, longitudinal opening of near. 100) and a second working channel port (Fig. 7F, longitudinal opening near ref. 348) extending through said distal portion in communication with one another (Fig. 7F) and in communication with said proximal chamber (Fig. 7F) wherein said first and second working channel ports together form a substantially oval cross-sectional shape (Fig. 7E); and a central distractor (Fig. 7F, ref. 100) in said chamber of said guide sleeve housing, said central distractor including a distractor tip (Fig. 7F, ref. 102) movably positionable between said first and second working channel ports, said distractor tip including upper and lower

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distraction surfaces (Fig. 8, ref. 102, upper and lower surfaces of ref. 102) defining a distraction height therebetween to maintain distraction of a spinal disc space (Fig. 8, height between surfaces of ref. 102). The proximal chamber is sized to receive a distal end of a guide sleeve (Fig. 7F). The tip of said central distractor is centrally located in said housing, since it is in between the sidewalls of the device. The central distractor is rotatable from a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space to a distraction configuration whereby said upper and lower distraction surfaces are oriented toward vertebral endplates of the spinal disc space. The guide sleeve housing is removably engageable to a housing inserter. The central distractor includes a shaft extending proximally from said tip (Fig. 7F, shaft of reference 100). The housing inserter and said guide sleeve housing are positionable over a proximal end of a shaft of said central distractor and movable therealong to position said guide sleeve housing in said operative position. The inner wall defines a groove therein, since the inner wall generally defines a round wall, so a portion of the circle that it defines can be considered to be a groove. The central distractor includes a housing engaging portion (Fig. 7F, ref. 110) having an actuatable finger (Fig. 7F, ref. 110) for removably engaging said groove of said guide sleeve housing. The central distractor tip includes a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space and said finger is not engaged to said guide sleeve housing; and said central distractor tip is rotatable to a distraction

configuration from said reduced height configuration whereby said upper and lower distraction surfaces are orientable toward vertebral endplates of a spinal disc space and said finger is actuated and received in said groove thereby coupling said guide sleeve housing to said central distractor. The guide sleeve housing is removably engageable to a housing inserter, said housing inserter having an actuatable finger positionable to engage said housing inserter to said guide sleeve housing. The housing inserter and said guide sleeve housing are positionable over a proximal end of said shaft of said central distractor and movable therealong to position said guide sleeve housing in an operative position adjacent the spinal disc space. The central distractor is withdrawable from said guide sleeve housing. The instrument further comprises a guide sleeve (Fig. 7F, ref. 420) engageable to said proximal-portion of said guide sleeve housing. The first working channel port and said second working channel port of said guide sleeve housing are in communication with one another through said guide sleeve housing, since they are both curved (Fig. 7E). The guide sleeve housing includes a pair of lateral flanges (Fig. 7F, ref. 342) extending distally therefrom on opposite lateral sides of said guide sleeve housing. Each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof (Fig. 7F). When in an operative position said proximal portion of said guide sleeve housing includes a first width transverse to the spinal column axis and said distal portion includes a second width transverse to the spinal column axis, said first width being greater than said second width (Fig. 7F, since the device comprises multiple widths).

Michelson discloses a spinal surgical instrument comprising a shaft (Fig. 7F, ref. 100) an engaging portion at a distal end of said shaft (Fig. 7F, portion above ref. 102) releasably engageable with a member (Fig. 7F, ref. 340) positioned about said engaging portion, wherein said member is a guide sleeve housing (Fig. 7F, ref. 340) defining first and second access ports (Fig. 7F, ports near refs. 100 and 348) therethrough for accessing a spinal disc space with said engaging portion removed therefrom, said access ports being in communication with one another (Fig. 7F) and together defining a substantially oval cross-sectional shape through said guide sleeve housing (Fig. 7E); and a distractor tip (Fig. 7F, ref. 102) extending distally of said engaging portion, wherein said engaging portion includes an enlarged configuration (Fig. 7F, since the engaging portion comprises the portion between refs. 110 and 102, both of which are narrower than ref. 100) relative to said shaft and said distractor tip. The distractor tip is rotatable relative to said engaging portion between a distraction configuration to a reduced height configuration, since the distractor tip gets screwed on to the engaging portion (Fig. 2). The distractor tip includes an upper distracting surface and an opposite lower distracting surface (Fig. 8, upper and lower surfaces of ref. 102). At least one of said upper and lower distracting surfaces includes a vertebral endplate engaging surface (Fig. 8). The engaging portion includes a receptacle (Fig. 7F, indented portion between refs. 102 and 100) and a finger (Fig. 7F, ref. 344) movable into and out of said receptacle between an engagement position for engaging said member positioned about said engaging portion and a release position for releasing said member from said

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engaging portion. The distractor tip is movable between a distraction configuration wherein said finger engages said member and a reduced height configuration wherein said finger is released from said member. The guide sleeve housing includes a pair of lateral flanges (Fig. 7F, ref. 342) extending distally therefrom on opposite lateral sides of said guide sleeve housing. Each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof (Fig. 7F, ref. 342).

With regard to the statements of intended use and other functional statements (e.g. ...movably positionable..., ...to receive a distal end of a guide sleeve..., ... removably engageable to a housing inserter...), they do not impose any structural limitations on the claims distinguishable over the device of Michelson, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER